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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09 359,181 | 07 22 1999 | GERARD GRASSY | 1028-1 | 2476 |

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SUITE 720
1601 MARKET STREET
PHILADELPHIA, PA 19103-2307

EXAMINER

CLOW, LORI A

| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 05/21/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,181

Applicant(s)

GRASSY ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-68 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) 3,11-17,21-68 and 70-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,8-10 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim 10 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiply dependent claim (claim 9). See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections-35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 8-10, and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims do not disclose how to practice the invention. Simply "building", "selecting", and "modeling", without any concrete active steps such that one of skill in the art could practice the invention without undue experimentation, does not constitute enabling the said invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or

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absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able to provide, identify, and describe molecules that exhibit a desired activity by modeling, building, selecting, and filtering.

b) The specification provides examples for a computer-aided method of describing a molecule.

c) The specification provides working examples of a set of 19 peptides used as a learning set to define a strategy for rational design.

d) The invention is drawn to a method for identifying and describing a molecule with a desired activity.

e) It would have been well known in the art that molecular modeling can be computerized such that molecular descriptors are used to define the molecule of interest. Furthermore, the descriptors can be used to compare to libraries of known and unknown molecules for several iterations in order to identify candidate molecules. The filtering of molecules is also known in that it provides a means of narrowing computational burden and identifying specific candidates. The instant application, however, fails to provide concrete active steps such that one of ordinary skill in the art could practice the invention. Specifically, method steps that adequately describe the process of computationally determining molecular descriptors are not disclosed. What methods of computation are used? Furthermore, the process for building a combinatorial library using the molecular descriptors is not defined in such a way as to practice that step.

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- f) The skill of those in the art of molecular modeling is high.
- g) The prior art indicates molecular design methods using descriptors.
- h) The claims are broad because the claims are not limited to any particular steps, in any particular order that specifically teach how to practice the said invention.

Claims Rejections-35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 5, 8-10, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krieger (Chemical and Engineering News (12 February 1996) vol.74, no.7, pp.67-73) in view of Platt et al. (US Patent 5,784,294).

Krieger discloses methods of selecting desired compounds using a variety of methods and method steps, including: a library building step (p. 67, col. 3), a modeling step (the virtual library in virtual space) (p. 68), comparing and filtering against databases, or for particular properties (p. 68). QSAR modeling can also be performed (p. 69). The reference further discloses a collection of software that comprises combinatorial chemistry software applications, molecular modeling software, and a data access and management application which allows filtering of data by various means and descriptors. The C2-diversity product provides for combinatorial library building and selection based on various 2-D and 3-D descriptors for QSAR methods of identifying particular compounds with various potential properties. Krieger does not, however, teach the specific limitation of descriptors that are defined by conformational variations, i.e. shape change.

Platt et al. do teach a computer-based method and system that describes molecules using a set of attributes of the molecule derived from data representing the atomic structure and atomic charge of the molecule. These attributes include the **shape** of the molecule as defined by the moment of inertia of the molecule, the charge distribution of the molecule, and/or attributes that represent the relationship of the shape to the charge distribution of the molecule. These attributes may be used for molecular matching and activity prediction, as well as in 3-D QSAR

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analysis (see abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Kreiger so as to include the further step of conformational variation as a descriptor, as taught by Platt. In fact, Platt gives numerous ways in which to use the COMMA model, one of which includes QSAR modeling (col. 4, paragraph 1). Therefore all of the limitations of the instant application claims are met.

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10A.M. to 6P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 16, 2002
Lori A. Clow, Ph.D.
Art Unit 1631

Lori A. Clow



MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
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